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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/530,790	04/08/2005	Hideko Kosaka	10873.1670USWO	9379

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EXAMINER	
WHITE, DENNIS MICHAEL	

ART UNIT	PAPER NUMBER
4151	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/530,790	KOSAKA, HIDEKO	
	Examiner	Art Unit	
	DENNIS M. WHITE	4151	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *08 April 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-16* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-16* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *08 April 2005* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *06/22/2005*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 1-4, 6, 8, 15-16 are rejected under 35 U.S.C. 102(b) as being anticipated by Fischer et al (US 4,275,031).

Regarding claims 1-4 and 6, Fischer et al teach a test kit (piece) (col. 6 lines 19-24) used in medical laboratory diagnostic tests (col. 1 lines 11-13) comprising: Chromazurol S (reads on formulas 1-4) or Eriochrome cyanine (reads on formula 6) (col. 4 lines 29 and 33). The test kit is fully capable of being used on creatinine measurements.

Regarding claim 8, Fischer et al teach a second film over the reagent zone in such a way that a hollow space is open on two sides ("compound is included in a porous material") (col. 6 lines 34-39).

Regarding claims 15-16, Fischer et al teach the use of the organic polymers, such as polyvinylpyrrolidone (PVP) and polyvinyl alcohols (PVA) (col. 3 lines 37-44) with a ratio of reagent (compound) to polymer that can vary between 10:1 and 0.1:1 (reads on "ratio (molar ratio A:D) of 50:1 to 3:1") (col. 6 lines 12-15). PVP and PVA of Fischer are identical to those compounds indicated as nonionic surfactants in the Applicant's specification (Page 7 lines 21-25).

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

4. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

5. Claims 5 and 7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fischer et al (US 4,275,031).

Regarding claims 5 and 7, Fischer et al teach the compounds Chromazurol S (reads on formulas 1-4), Eriochrome cyanine (reads on formula 6), or pyrocatechol-3,5-disulphonic acid (col. 4 line 66) for diagnostic testing, but are silent about of Chromazurol B of claim 5 and pyrocatechol violet of claim 7. Structural similarities have been found to support a prima facie case of obviousness. See, e.g., In re May, 574 F.2d 1082, 1093-95, 197 USPQ 601, 610-11 (CCPA 1978) (stereoisomers); In re Wilder, 563 F.2d 457, 460, 195 USPQ 426, 429 (CCPA 1977) (adjacent homologs and structural isomers); In re Hoch,

428 F.2d 1341, 1344, 166 USPQ 406, 409 (CCPA 1970) (acid and ethyl ester); In re Druey, 319 F.2d 237, 240, 138 USPQ 39, 41 (CCPA 1963) (omission of methyl group from pyrazole ring). Generally, some teaching of a structural similarity will be necessary to suggest selection of the claimed species or subgenus. See also In re Hoeksema, 399 F.2d 269, 158 USPQ 596 (CCPA 1968) (A claim to a compound was rejected over a patent to De Boer which disclosed compounds similar in structure to those claimed (obvious homologs) and a process of making these compounds). Therefore, it would have been obvious to one of ordinary skill to substitute chromazurol B or pyrocatechol violent as known equivalents of chromazurol S, Eriochrome cyanine, or pyrocatechol-3,5-disulphonic acid to obtain the expected result of indicators capable of color changes.

6. Claims 9-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fischer et al in view of Pugia (US 5,374,561).

Regarding claims 9-11, Fischer et al teaches the limitations of claim 1 as per above, but is silent about the compound further comprising a metal or its salt that forms a colored complex with the compound, wherein the metal is a transition metal from a group consisting of Cu (II) and Pd (II). Pugia teaches a creatinine assay using soluble cupric salt (reads on "metal or its salt", "transition metal", and "Cu (II)"), hydroperoxide and an oxidizable indicator (Pugia: Abstract). It would have been obvious to one of ordinary skill in the art at the time of the invention to use a soluble cupric salt with the test kit of Fischer et al in the measurement of creatinine to form a colored complex with the indicator as

motivated by Pugia (col. 1 line 62-col. 2 line 6) because it allows the measurements to be done at neutral pH, instead at high pH, thus avoiding the carriers, such as filter paper, from becoming brittle and overcoming the difficulty of obtaining even distribution of the alkali throughout the carrier matrix.

Regarding claim 12, Fischer/Pugia teach the compound A and the metal or its salt, but are silent about a molar ratio of 30:1 to 1:15 of compound A to metal or its salt. This ratio is result effective because the adding of a metal or its salt to the compound A is done in order to make a colored complex at a neutral pH. Adding too little metal will give no color change and adding too much metal will provide excess metal that will interfere with the reaction with creatinine. Therefore, it would have been obvious to one of ordinary skill to optimize the ratio of metal or its salt to the compound A in Fischer/Pugia in order to obtain a proper color change of the complex of compound A and the metal or its salt.

Regarding claim 13, Fischer/Pugia teach the use of a succinic acid buffer (buffer agent) (col. 4 lines 34-35).

Regarding claim 14, Fischer/Pugia teach the buffer to maintain the pH at 7.0, but are silent about the ratio of the indicator ("compound") to buffer agent being 1:10 to 1:1000. It would have been obvious to one of ordinary skill at the time of the invention to optimize the ratio of the indicator to the buffer in order to obtain the expected result of maintaining the desired pH.

Conclusion

7. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Lau (US 4,960,710) teach composition for determining the presence and concentration of low to trace amounts of proteins, wherein the reagent composition is incorporating into a carrier matrix comprising: a dye, such as pyrocatechol violet; a tungstate, such as ammonium tungstate; and, if necessary, a suitable buffer, is incorporated into the carrier matrix.

Nomura et al (DE 3602999 A1) teach Microcapsules in which a chelating agent is incorporated are labelled either with an antigen or with an antibody. These microcapsules are introduced together with a metal salt, a supplement and a sample containing an antibody to be determined or an antigen to be determined into a reaction vessel. The immunological reaction induced thereby releases the chelating agent, for example Chromazurol B, from the microcapsules, and it binds the metal ion with formation of a colour. The coloured reaction solution is then determined by photometry and the concentration of the antibody or antigen to be determined is found from the extinction at a particular wavelength.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to DENNIS M. WHITE whose telephone number is (571)270-3747. The examiner can normally be reached on Monday-Thursday, EST 9:00-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Kornakov can be reached on 571-272-1303. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Dmw

/Michael Kornakov/
Supervisory Patent Examiner, Art Unit 4151